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10/054,458 28-May-02 Egberink, et al 2000.602 US

Title: PHARMACEUTICAL FORMULATION OF GEPIRONE FOR ORAL ADMINSTRATION

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LICENSING & REVIEW

Please find attached a communication from the Examiner regarding the Petition for Retroactive License under 37 CFR 5.25.



United States Patent and Trademark Office

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UNITED STATES PATENT AND TRADEMARK OFFICE
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In re:

Egberink et al.

:DECISION ON REQUEST

Serial No.:

10/054,458

:UNDER 37 CFR 5.25

Petition Filing date:

May 28, 2002

Docket No.:

2000.602 US

Title: PHARMACEUTICAL FORMULATION OF GEPIRONE FOR ORAL ADMINISTRATION

37 CFR 5.25(a) requires the following:

- 1. A listing of each of the foreign countries in which the unlicensed patent application material was filed,
- 2. The dates on which the material was filed in each country,
- 3. A verified statement (oath or declaration) containing:
 - i. An averment that the subject matter in question was not under a secrecy order at the time it was filed abroad, and that it is not currently under a secrecy order,
 - ii. A showing that the license has been diligently sought after discovery of the proscribed foreign filing, and
 - iii. An explanation of why the material was filed abroad through error and without deceptive intent without the required license under \$ 5.11 first having been obtained, and
- 4. The required fee (\$ 1.17(h)).

The petition is Denied at this time in that the petition is defective since the requirements set forth in 37 C.F.R. 5.25(a)(2)(3)(iii) have not been met.

There appears to be no error as to why the material was first filed abroad.

Dr. Broekkamp states (Declaration, page 2) that "it is habitual practice in our department in the Netherlands, to prepare an application for patent, file the application and investigate in detail *later* which persons should be named as co-inventors."

It appears that it was merely reliance on European law and not lack of knowledge of the requirements of US laws that prevented a thorough investigation of inventorship.

Having knowledge of the US foreign filing requirements should have urged the investigation of inventorship prior to filing even though not required by European law. Not determining inventorship until later in the prosecution process is not within the meaning of "error" as provided in 37 CFR 5.25(a)(3)(iii).

Thus, in the absence of the declaration explaining why the material was filed abroad through error, the provisions of 37 CFR 5.25 have not been met.

There is no record with respect to 10/054,458, of any response to the initial denial mailed on July 29, 2002. Therefore, THIS ACTION IS MADE FINAL. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing of this action. Extensions of time may be had under 37 C.F.R. 1.136(a).

Yvonne R. Abbott Patent Examiner (703) 308-2866